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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,247	07/12/2004	Detlev Neuland	01/090LTS	5234

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EXAMINER	
HELM, CARALYNNE E	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
09/06/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,247	NEULAND ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1 and 5-12* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1 and 5-12* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods when the carrier is a polymer and the diffusing contaminant is flavors and/or fragrances as well as methods when the carrier is paper, does not reasonably provide enablement for full claimed scope of carriers and diffusing substances in the recited methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level:

The invention relates to methods of removing diffusion contaminants from a carrier material previous employed as a casting substrate for a drug, food, or cosmetic film. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. Here a carrier material must be employed that is susceptible to diffusion of substances found in the coating. The applicants highlight drugs as particular contaminating substances of interest as well as particular materials that are envisioned as the carrier (see instant specification page 2 lies 19-26 and page 2 line 28-page 3 line 5). The envisioned films employed for the carrier that are also embraced by the claims were composed of paper, thin metal foil, polyethylene, polyvinylchloride, polyvinylidenechloride, polyesters, or siliconized paper where this last variety is preferred. As a fibrous, porous material, an uncoated paper film would be susceptible to diffusion of drug; however, most of the envisioned carrier materials are not. Panoz teaches that aluminum foil is impermeable to drug (see US Patent No. 4,592,753 – column 4 lines 54-56 and 58-60). Theeuwes et al. teach

partition materials for impermeable barriers in a drug delivery device and name high density polyethylene, polypropylene as well as polyethylene coated foil as envisioned barriers for this purpose (see US Patent No. 4,455,143 - column 7 lines 7-12, 14-18, and 53-57). Fisher et al. teach a film of polyethylene or polypropylene as a drug impermeable barrier on a drug delivery system (see column 5 lines 6-8). Berner et al. (US Patent No. 5,064,654) teach a transdermal device composed of a reservoir formed between a permeable membrane and impermeable backing layer that is impermeable to ethanol drug and water (see column 3 lines 28-31). This impermeable material is envisioned as high, medium, or low density polyethylene, polypropylene, polyvinylchloride as well as polyvinylidene chloride (see column 7 lines 36-40 and 45-48). In addition, Solomon et al. teach that siliconized paper is naturally impermeable to drugs (see US PGPub No. 2005/0287195 - paragraph 52). Consequently, most of the particular envisioned carrier materials, which includes the most preferred carrier, are not susceptible to diffusion by drug since the prior art identified them as being impermeable to drugs. Although the instant disclosure notes that the temperature and time for thermal exposure sufficient to remove essentially all of the contaminant can be determined by conventional means, there is no guidance as to the nature of these conventional means or if they can also be used to predict whether a material is susceptible to diffusion by substances in the removed film composition. Therefore it is not predictable whether the contaminant of most concern in the disclosure or any other ingredient of the film would be able to diffusion into a carrier of the invention

2. The breadth of the claims:

The claims recite contamination of the carrier by a "substance" in the coating that is applied to and peeled from the carrier. Thus every ingredient included in a coating composition is a candidate for contaminating the carrier. Additionally, the carriers that become contaminated are not limited. Further, the amount of material that must be removed is broadly recited as is the temperature and duration of thermal exposure employed to achieve the removal.

3. The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples in the disclosure. In addition, there is insufficient guidance provided such that the artisan would be able to predict which carrier materials would be susceptible to diffusion and thus fall within the bounds of the invention because the most preferred carrier and most of those named are outside the invention.

4. The quantity of experimentation necessary

In order the practice the invention, the artisan would be required to perform a host of experiments which would present an undue burden. Since applicants have provided no guidance concerning testing methodologies, the artisan would have to seek out a testing scheme that would be sufficiently sensitive to accurately measure the presence of diffusion products in a film as well as the rate of any diffusion that occurs. In addition, the artisan would have to determine if the time scale over which any assessed

diffusion occurred was relevant to the coating method (e.g. would the contaminant be in contact with the carrier long enough during the coating process to diffuse into the carrier). The artisan would also have to develop some way to determine if the assessment was representative of the exposure conditions (e.g. substance concentration, exposure temperature, etc.). These experiments would have to be conducted with every combination of carrier and ingredient in the coating composition. If any combination was found to be susceptible to diffusion over the coating period, it would then have to be assessed to determine if the substance could then be removed within approximately 0.5 to 6 minutes at approximately 80ºC via assessment techniques that the applicants have not disclosed. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Response to Arguments

The applicants' arguments, filed July 10, 2012, have been fully considered. The objections to the specification and claims are hereby withdrawn in light of the amendments. The arguments directed toward the species where the carrier is a polymer and the contaminants are flavors and/or fragrances are persuasive; however the remaining species stand as rejected under 35 USC 112, first paragraph.

The applicant argues that the claims are not directed to permeation of the contaminant within the carrier, but instead to the "removal of contaminants absorbed on

or in the carrier's surface". The claims recite removing substances that are in the carrier by "diffusing into and thereby contaminating said carrier material." Prior art recognized the need to clean carriers due to contamination on their surfaces; however the claims are limited to materials that have penetrated the surface of the carrier by diffusion which is not the same as those which have "absorbed on or in the carrier's surface".

Attorney arguments cannot stand in the place of evidence. While the discussion of the observations from preparing Listerine® strips are noted, this information does not qualify as evidence on the record to be considered in the analysis of the patentability of the instant claims.

The applicant further highlights the discussion provided by the Willige thesis to provide support for the idea that the absorption of components into polymer films was known in the food packing industry. The discussion of absorption into polymers used in packing by Willige is focused on flavors. The instant claims are not limited to flavors as the diffusing contaminant, but broadly claim "substances" in general. This requires that one of skill in the art be able to predict which substances are able to diffuse into a carrier being employed under the coating conditions employed and also removed within the time and at the temperature specified such that the invention can be practiced. The applicant additionally classifies plasticizers and colorants that are discussed by Willige as migrating out of polymer packing materials, as adjuvants envisioned by the instant invention which is not supported by the instant disclosure.

The applicant also argues that the impermeability of various carriers of the invention noted in the rejection is not relevant to their susceptibility to diffusion since the

invention is limited to diffusing materials. This discussion in the rejection was presented particularly in reference to drugs which the instant disclosure and claims indicate as a contaminating substance in the claimed method. As indicated in Willige, absorption requires molecules to adsorb and diffuse into a material while permeation requires both of these steps as well as diffusion through the material and desorption (see figure 1.8). This argument by the applicant suggests that drugs would be able to adsorb to the polymers, diffuse into their surface, and for some reason that was not noted by the applicant, be unable to continue diffusing and desorb from the polymer. The references cited regarding the impermeability of the polymers to drug do not suggest that the polymer or polymer coated paper were treated in any way to impede diffusion beyond the surface or preclude desorption. Thus there is no reason of record which indicates that drugs would diffuse into the polymer and polymer coated paper materials that re taught to be impermeable to drugs. Further, the discussion presented by Willige does not concern itself with phenomena of flavor movement beyond absorption and makes no statement that diffusion through and desorption from these materials does not also happen.

The applicant goes on to argue that Willige found that polyethylene easily absorbs a number of aroma compounds. However, Willige only discussed low density polyethylene (LDPE) in these data that the applicant highlights. Charara et al. (Journal of Food Science 1992 57:963-968) tested a much wider array of flavors and saw a similar trend but that nearly a third of these same compounds were not absorbed by high density polyethylene (HDPE) (see table 2). Charara et al. note that the crystallinity

of the polymers was responsible for this difference since absorption and diffusion takes place in the amorphous and low crystallinity regions of the polymer while crystal structure impeded diffusion (see page 965 column 1 paragraph 1). Thus the more crystalline HDPE did not absorb all the flavor compounds. Additionally, the LDPE and HDPE did not follow the same trends regarding the ability to support flavor diffusion. Octylacetate and undecanal were among the flavors that were not absorbed by HDPE, but these flavors were not amongst the flavors that were absorbed the least by LDPE. Similarly, an examination of the behavior of dodecanal, undecanal, and decanal which are linear compounds that only differ in the length of their carbon chain of 12, 11, or 10 atoms, respectively, points to some unpredictability of assessing whether one compound will diffuse into a given polymer based upon its behavior in another polymer. More of the 11 carbon flavor was absorbed by LDPE than the 12 carbon flavor while HDPE did not absorb the 11 carbon variety at all but did absorb the 11 carbon variety to a small degree. The chemical structures of the other tested flavors vary and include a variety of different shaped monocyclic structures as well as small systems of fused ring structures. As a consequence of these different structures, the ability to predict their ability to diffuse into an untested polymer carrier is not supported by the disclosure or prior art. Unlike the discussion of Charara et al. and Willige, the compounds at issue for diffusing into the carriers in the instant claims are not limited to flavors but are considerably more diverse embracing countless drugs that include structures much larger than flavors, cosmetic actives, and ingredients found useful for inclusion in drug, food, or cosmetic containing films.

It is additionally noted that most solid metals (e.g. aluminum) are completely crystalline materials and as a result would not support the diffusion of molecules on the size scale of drugs or the multi-atom molecules embraced by the claimed diffusional contaminants. The discussion provided by Willige does not discuss absorption of any molecules into solid metals and the applicant does not suggest that their findings in LDPE influence the lack of predictability of practicing the claimed method with a metal foil carrier.

The applicant additionally argues that gas chromatography can be employed to assess the amount of contaminant that has diffused into a carrier. After an extraction, this technique can be used to quantify the amount of contaminant in the extract but it is not capable of indicating where the contaminant originated in the carrier. The extraction technique employed by Willige collects flavor compounds that are adsorbed to the outside surface of the tested polymers as well as what may have diffused into the material but it neither distinguishes nor separates the two from one another.

Further, the applicant argues that the claims were amended to recite active agents, adjuvants, flavors or fragrances as contaminants thus every ingredient in a coating composition need not be tested for its ability to diffuse into the carrier. While some claims have this limitation, multiple claims (e.g. claims 1 and 7) still recite "substances within the coating" as contaminants which embraces all the ingredients in the coating as possible contaminants.

The examiner concurs with the applicant that working examples are not a requirement in the application. However in light of the unpredictability suggested by the

prior art and the lack of general guidance in the specification, the absence of working examples does not favor the full enablement of the invention. The applicant additionally argues that Willige indicates which polymers would be susceptible to diffusion. The discussion of Willige details a series of polymers that are susceptible to the diffusion of some flavors, but these examples are not representative of the breadth of compounds that the claims embrace as diffusional contaminants.

In light of the breadth of compounds embraced as possible contaminants and the lack of correlation between the findings of Willige concerning flavor diffusion and the diffusion of drugs, adjuvants, as well as food and cosmetic active ingredients, the amount of experimentation required to determine 1) whether a coating ingredient diffuses into a given carrier within the duration and under the conditions of their contact and 2) whether those that do are also able to be removed from the carrier at the temperature and time duration recited is undue.

Allowable Subject Matter

The prior art recognized a desire to clean carrier belts that are employed for the production of cast polymer matrices (e.g., films). A variety of techniques, which include thermal treatment, were taught for this end. Carrier materials envisioned and recited by the instant claims are taught in the prior art and the desire to clean these materials was also recognized. However, the art did not highlight the mechanism by which contamination occurs. Thus the recognition of contamination by diffusion is not discussed in the prior art. As a carrier material known for use in film casting process

lines that would also be susceptible to diffusion of coating materials due to its porous nature, the instant method where uncoated paper is the carrier would be enabled and free of the art.

In addition, given the teachings of Willige describing the ability of various flavors to diffuse into various polymer films, the further discussion of the phenomenon described by Charara et al., and the similar issue occurring in with fragrances as detailed by Peacock (Handbook of Polyethylene Marcel Dekker Inc:New York 2000 pg185-187 especially page 187 lines 1-14), the practice of the invention when the carrier is a polymer and the diffusional contaminating substance is a flavor and/or fragrance is sufficiently enabled by the prior art that the invention could be practiced without undue experimentation.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
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